Section 14. Behavioral Measures

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This section contains information on behavioral research procedures performed in MTN-023; including the behavioral ACASI assessments, the In-Depth Interview (IDI) and SMS adherence assessment and correspondence.

14.1 Overview

Behavioral assessments will be captured through web-based ACASI, IDIs, and SMS assessments. All behavioral interviews are source documentation and must be maintained in accordance with the guidelines for other study documentation.

Table 1 outlines the timing (by study visit) and mode (by instrument) each behavioral assessment should be completed.

Table 1
Behavioral Assessments: Timing and Mode of Administration

Questionnaire	Mode of Administration	Visit
Baseline	ACASI	Enrollment (visit 2)
Follow-up	ACASI	12 & 24-Week Study Visit
In Depth Interview (IDI)	Web Video interview	24-Week Final Clinic Visit or Early Termination Visit
SMS Messages	Frontline Software & Cell Phone	Weekly

14.2 ACASI Behavioral Assessments

The baseline behavioral assessment and follow-up assessments will be captured through Audio Computer Assisted Self-Interview (ACASI) at the Enrollment visit and Weeks 12 and 24 study visits.

The baseline behavioral assessment will evaluate a participant's past sexual behavior, concerns about using the ring, HIV concerns and partner HIV status. Follow-up assessments will explore participant experience using the ring, concerns about the ring, partner experience and adherence. Adherence questions will evaluate the consistency and timing of treatment administration and factors influencing adherence.

Once the participant has been welcomed, staff should introduce themselves and complete the following:

1. Explain the ACASI procedure.
    a. Stress we are using ACASI to give as much privacy as possible.
    b. Emphasize the responses are kept confidential.
    c. Tell the participant what to expect during the ACASI interview.
2. Enter information into the Administrative Section.
3. Swivel the laptop's screen toward the participant.
4. Demonstrate the use of the touch-screen computer, headphones and stylus.
5. Verify the participant's comfort using the touch-screen computer and stylus.
6. Allow the participant to complete the practice questions, assisting her, if needed, to make sure she understands how to answer.
7. Once the practice has been successfully completed, ensure the participant has read and understands the statement encouraging her to respond to all questions as truthfully as possible.
8. Inform the participant that you will be just outside the interview room. Instruct her to let you know if she has questions and when she is finished with the questionnaire.
9. When ACASI is finished, thank the participant and make sure she returns the stylus or leaves it with the computer.
10. For ACASI questions or concerns, email: mtn023acasisupport@mtnstopshiv.org.

Detailed guidelines on ACASI equipment set-up, maintenance, trouble shooting and ACASI administration are addressed in the MTN 023 ACASI User's Manual, located on the MTN-023 Study Implementation Materials Webpage (http://www.mtnstopshiv.org/node/5444).

14.2.1 Data Collection: ACASI

Each participant will complete behavioral questionnaires by ACASI at the Enrollment, Week 12 and 24 visits. Each study site must have a computer connected to the internet and speakers with a headset. The computer must be in a private room where participants will not be interrupted or overheard. Select a location in a room with a door that closes to allow privacy for the participant.

Details on how to access the ACASI questionnaires are included in the ACASI User's Manual, located on the MTN-023 Study Implementation Materials webpage.

14.2.2 Missed Visits

Participants who miss their scheduled visit and ACASI may reschedule their visit, if within the visit window. Missed interviews should be noted in participant chart notes and every effort should be made to reschedule the interview. If the interview cannot be conducted within the visit window, the MTN-023 Behavioral Team coordinator (jndmoore@ucla.edu), and MTN-023 Management Team should be contacted to assess whether the interview should be conducted at a later date.

14.2.3 Interrupted Visits

Site staff should ensure that ACASI questionnaires are always completed at the appropriate scheduled visit, and that all ACASI data from a given questionnaire is collected during the visit. If a participant is interrupted and does not complete an ACASI questionnaire in one sitting, based on site staff judgment and length of interruption, she can complete the ACASI questionnaire later as long as it is **during the same visit**. In the case of a split visit, the ACASI may be completed on any day a participant is at the clinic during the same visit.

If participants need to briefly interrupt their computer sessions (i.e. attend to a call, go to the bathroom), at the discretion of the site staff, they can do so, and resume the ACASI where they left it, as long as the survey window remains open. However if the computer window is closed before the ACASI is completed, participants will need to start a **new** ACASI questionnaire from the beginning. If participants need to leave the clinic in the middle of the ACASI, resulting in a split visit, they must close the interview window and begin a new ACASI questionnaire when they resume the visit.

If duplicate ACASI questionnaires are present for the same PTID and date, the fully-completed ACASI questionnaire will be the one used in study analyses. These unique circumstances should be documented in the clinic chart notes and a brief description recorded on the applicable CRF (i.e. Enrollment, Follow- up ACASI Tracking).

14.2.4 Management of Errors on ACASI

Once an ACASI questionnaire is completed, no one can change the responses or administrative fields, including site staff. If errors are noted by site staff for the administrative section (or by participants to the site staff on the questionnaire section), notify the ACASI troubleshooting team via email at mtn023acasisupport@mtnstopshiv.org. Please include the following information in the message text: PTID, date, visit code, the name of the ACASI questionnaire and a description of the error. Also, to facilitate the troubleshooting process, please indicate in your email a description of the problem, including a copy of the error message(s), if any, and date and time of when the problem occurred. The ACASI troubleshooting team will assess the problem and communicate with site staff about resolutions. If this occurs, it should be documented by keeping a record in the participant's file.

14.3 In-Depth Interview (IDI)

At the 24-Week Final Clinic Visit/Early Termination Visit, a subset of approximately 36 randomly selected participants across all sites, (approximately 6 per site) will complete an IDI. Participants are randomly assigned to the IDI via the randomization envelope and prescription at the Enrollment Visit. The interview will address study vaginal ring use and acceptability during the trial. These interviews will be conducted by a trained qualitative interviewer and will follow a semi-structured questionnaire guide and are anticipated to last approximately 45-60 minutes. These interviews will be conducted over the computer by a non-recorded video. If the participant consents, an audio recording will be made with a digital audio recording device that is operated by the qualitative interviewer (off-site at UCLA). The audio from the interview will be recorded and transcribed for analysis.

Through open-ended questions, this interview will explore the participant's overall experiences and feelings using the ring during the trial, including any physical, mental or emotional concerns or experiences she encountered; her experiences using the ring; her and her partner's attitudes towards the ring, including during sexual intercourse, preferences for HIV prevention.

The staff member should explain that these questions are being asked in person to more thoroughly explore the participant's feelings, and that her responses will be audio recorded but not video recorded.

Further description of the management of audio files, interview notes, debriefing reports and transcripts of the interviews is described below.

14.3.1 Scheduling the IDI

Study coordinators will email the off-site qualitative interviewer to inform her of all scheduled appointments so they can prepare for video calls. The interviewer will confirm the appointment via email. The interviewer should be informed of all changes or cancellations within 24 hours of the scheduled appointment, if possible. If last minute changes do occur, please notify the interviewer as soon as possible by phone or text message. Any scheduling changes will be confirmed by email.

To minimize scheduling conflicts between sites, the interviewer will enter available hours and confirmed appointments in an Outlook calendar shared between the sites. Study coordinators can view the calendar prior to scheduling appointments to make sure the interviewer will be available to do the interview.

To access the calendar, go to Outlook on the study provided laptop and sign in with account login below. Click on the "Calendar" tab at the bottom left.

For last minute changes to scheduling or to notify interviewer that participant is ready, call listed phone number or send text message. For non-urgent matters and advanced scheduling, use email.

Contact: Janell Moore Phone: (510)717-9952
Email: jndmoore@ucla.edu

Bronx Site Login
Email: Bronx023SMS@ucla.edu
Password: 023IDIConnect

Boston Site Login
Email login: Boston023SMS@ucla.edu
Password: 023IDIConnect

UAB Site Login
Email login: UAB023SMS@ucla.edu
Password: 023IDIConnect

Denver Site Login
Email login: Colorado023SMS@ucla.edu
Password: 023IDIConnect

Pittsburgh Site Login
Email: ph_pitt023sms@ucla.edu
Password: 023IDIConnect

Memphis Site Login
Email: ph_memphis023SMS@ucla.edu
Password: 023IDIConnect

14.3.2 Preparing for the IDI

Before each IDI the following should occur:

Qualitative Interviewer:

- Ensure the correct version of the guide and other supplemental tools (e.g. ring model or picture to use as a reference for describing issues related to the ring) are ready for use.
- Ensure the internet-based video system (ReadyTalk) is ready and connected and the interviewing space is ready.
- Contact the site to confirm the visit and time of the IDI.

Site:

- Ensure the participant was randomized to the IDI on the Randomization Envelope
- Ensure the computer with a webcam is available in a private space, and has a headset with microphone plugged into the computer that is operational.
- Ensure the internet-based video system (ReadyTalk) is ready and connected.

14.3.3 Data Collection: IDI

For the IDI, each study site must have a computer connected to the internet with a video camera and speakers with microphone or headset. The computer must be in a private room where participants will not be overheard during the interview. Select a location in a room with a door that closes to allow privacy for the participant and to allow the participant and interviewer to hear each other without noise disturbance. The participant should be able to sit comfortably and be seen on the video camera by the interviewer, and be able to see the interviewer on the screen. A neutral background behind the interviewer and the participant is preferable. To allow better viewing of the participant and interviewer, they should not be sitting in front of a bright window or other light that would disrupt the camera.

14.3.4 Initiating and Conducting the Video Interview

Prior to conducting any video interviews, the interviewer will verify that each site has completed video interview set up and ensure that all necessary add-on software is installed in the internet browser of the site's interview computer.

The site staff will contact the interviewer to let her know that the participant is ready. The interviewer will initiate a meeting in ReadyTalk and send an email invitation to the appointed site staff. The site staff will click on the link in the email from the study laptop to

join the meeting, log into the meeting and turn on the video feed. Once the connection is established and the video feed is running, the site staff will click to enlarge the video window. The site staff should help the participant get set up at the computer with the headset. The site staff will then leave the room and close the door.

The interviewer will welcome the participant to the IDI and review the IDI introductory checklist which reviews the content, length and confidentiality of the interview and ensures that the participant agrees to audio recording the session. If she agrees, the interviewer will start the recording. Following the last question on the IDI, the recording will be stopped. If she does not agree to audio recording, the interviewer will take long hand notes.

At the end of the interview, the interviewer should quickly review the guide and her notes for completeness and clarify with the participant any unclear parts or gaps in the notes.

Once the interview is done, the interviewer will thank the participant, and ask that they bring the site staff back into the room. The interviewer will confirm with the site staff that the in-depth interview has been completed and the interviewer will then end the video meeting. The interviewer will inform site staff of any potential adverse events (AEs) or social harms (SH) reported during the IDI.

Then the interviewer can further expand her notes (on the same day) to ensure completeness of the information, and complete a Debriefing Report that will be circulated for review to the behavioral qualitative team.

If any participant randomized to the IDI discontinues study participation early, or has a modified 24- Week Final Clinic Visit, but has completed at least 1 month of study, she may complete the IDI at study exit.

14.3.5 Qualitative Data Management for IDIs

14.3.5.1 Audio Files

The audio recording will be made with a digital audio recording device that is operated by the qualitative interviewer off site (BRWG). The audio recording will be completely separate from the computer video conference (that is not recorded).

Following the interview or discussion, the audio file should be uploaded onto a password protected hard drive. Audio files of IDIs will be destroyed following finalization of transcripts (transcript finalization process described below). The destruction process will be the responsibility of the BRWG study team. The audio recordings will be deleted from the server and a log will be kept noting the file, the date deleted, the signature of the staff responsible for the deletion, and a signature of another team member who witnesses the deletion.

14.3.5.2 Interview Notes

When an IDI is conducted, notes will be taken during each session to supplement the audio recording (or replace, if recording doesn't work or is refused). Immediately following the IDI, the interviewer reviews the guide, and adds or expands on notes and comments as needed. Interview notes will be filed in participant files in the BRWG offices that will be stored in a locked cabinet.

14.3.5.3 Debriefing Reports

On the same day as the IDI, the Interviewer should complete a Debriefing Report (DR) which will list basic information about the session and provide a summary report of the interview that can be used in "real time." A DR template will be developed by BRWG

Debriefing reports may be maintained electronically until final versions are provided by BRWG as described below.

At the BRWG, the DR will be read and reviewed by data team members and queries will be made on the DR using MS Word's comment feature within **one week** of receipt of the file. The following are examples of queries:

- Problems such as typos that lead to ambiguous meaning (e.g. "sore the medication" vs. "store the medication"), confusing terms or missing /potentially incorrect data
- Sentences that are unclear
- Clarification of local terminology or context
- Within **one week**, the Interviewer is asked to correct or clarify any problems identified directly in the DR text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within a comment bubble.
- When the revised information is received, the reviewer, the Qualitative Data Manager or a designated qualitative data team member reviews the corrected areas and deems the issue resolved or further follows up with the Interviewer until all necessary changes are made on the DR.
- Once the BRWG finds no additional issues, the BRWG will accept all changes, remove all comment bubbles and email the final clean DR to the Behavioral Qualitative Team. This final version of the DR should be printed and filed in the participant chart with the BRWG.
- After the DR is finalized, it will be circulated to the appropriate members of the Protocol and Management Teams.

14.3.5.4 Transcription

The audio recordings will be transcribed and will undergo the following QC process:

- Each transcript will be reviewed by a member of the BRWG's data team, and queries will be made on the transcript using comment bubbles. The QC may include the identification of the following:
    - Problems such as typos that lead to ambiguous meaning, confusing terms or missing/ potentially incorrect data
    - Sentences that are unclear
    - Clarification of local terminology or context
- Responses to queries will be made by another member of the BRWG data team by listening to audio recordings if necessary, Responses will be recorded either through changes directly in the transcript using track changes or through using the comment bubble in the reviewing mode of MS Word, when in-text changes are unable to be made. When changes in the text reflect content that was not spoken verbatim by the participant or interviewer, they will be inserted in [brackets].
- A designated BRWG staff member reviews the corrected areas and deems the issue resolved or further follows up as needed until all necessary changes are made.

Once the BRWG finds no additional issues, the BRWG will accept all changes, remove all comment bubbles, and finalize the transcript.

14.3.5.5 File Naming Conventions

All data files should be named according to a standard naming format. Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. For the first iteration of the file that is sent to the BRWG for review, there is no need to include the editor's initials. It is only upon subsequent review (QCing) that this occurs.

File Naming Conventions:

Initial format: [Interview Mode]_[PTID]_[Data Type]_[Date of IDI]

Query format: [Interview Mode]_ [PTID]_[Data Type]_[Date of IDI]_[Initials]

Final format: [Interview Mode]_ [PTID]_[Data Type]_[Date of IDI]_FINAL

For example, when reviewed for the first time, the IDI transcript ***"IDI_1001_Transcript_18NOV14"*** would become ***"IDI_1001_Transcript_18NOV4_CM"*** and ***"IDI_1001_Transcript_18NOV14_CM_NM"*** for the second revision. Once the document is finalized, all initials will be removed from the name and replaced with the word "FINAL."

14.3.5.6 Data Tracking

A Qualitative Data Tracking Log will be completed by the BRWG to maintain record of each audio file, DR and transcript that is submitted along with details regarding the submission date, query status, and finalization date.

14.4 SMS Messaging

Detailed instructions for SMS adherence assessment and correspondence are located in Section Appendix 14-4.

14.5 Special Cases and Technical Issues

14.5.1 Technical Problems Preventing ACASI or IDI Completion

In the event of technical problems (i.e. server or power outage) that would preclude a participant's ability to complete an ACASI questionnaire online, hard copy versions of ACASI questionnaires will not be available. These unique circumstances should be documented in the chart notes and a brief description recorded on the applicable CRF (i.e. Enrollment, Follow-up ACASI Tracking).

In the event of technical problems that interrupt or hinder a participant's ability to complete an IDI, 3 attempts to reconnect will be made and if none are successful the IDI will be rescheduled. These unique circumstances will be documented in chart notes and a brief description of the cause of the rescheduling will be recorded in the applicable CRF.

14.6 Staff Training

14.6.1 ACASI

Site staff that will be assisting participants with ACASI is required to complete at least 2 practice sessions for each instrument.

For testing, please access questionnaires through the websites indicated above. The following test PTIDs should be used:

Administrator ID's assigned by site:

- 100-199 – New York

- 200-299 – Birmingham, Alabama
- 300-399 – Denver, Colorado
- 400- 499 – Boston, Massachusetts
- 500- 599 – Pittsburgh, Pennsylvania
- 600- 699 – Memphis, Tennessee

Test PTIDs:

- 999-00062-2
- 999-00063-5
- 999-00064-8
- 999-00065-0
- 999-00066-3
- 999-00067-4
- 999-00068-9
- 999-00069-7
- 999-00070-1

Upon completion of testing at each given site, an email should be sent to the MTN-023 ACASI alias mtn023acasisupport@mtnstopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

14.6.2 IDI

Site staff that will be assisting participants with the IDI will be instructed in the use of the ReadyTalk video conference system. Prior to conducting any IDI at a site, the qualitative interviewer will assist site staff in setting up any software required to use ReadyTalk on the interview computer, and will instruct staff on how to connect participants to a video for the IDI. Site staff will participate in a mock interview with the qualitative interviewer to ensure the video system is operating correctly.

Prior to conducting any IDIs, clinic staff and the qualitative interviewer will be trained on the procedures for documenting and following up on reports of potential Adverse Events or Social Harms that participants may report during the IDI. The qualitative interviewer will be trained on the appropriate DAIDS procedures for safety reporting and file maintenance.

14.6.3 SMS

Site staff who will be assisting participants with the SMS will be provided detailed instructions on what information is needed by BRWG to set up messaging to participants. Prior to beginning SMS activities, a member of the behavioral team will walk site staff through the process. Site staff will participate in a test message exercise to ensure the system is operating correctly.

Detailed directions on the SMS setup and messaging procedures can be found in Appendix 14-4, at the end of this section. Site staff should familiarize themselves with these procedures and are welcome to test out the system prior to their formal training dat

Section Appendix 14-1: Quick Tips for In-Depth Interview

Scheduling

1. Schedule IDI in Outlook calendar:

- **Login email:**

  For UAB: UAB023SMS@ucla.edu

  For Boston: Boston023SMS@ucla.edu

  For Aurora: Colorado023SMS@ucla.edu

  For Bronx: Bronx023SMS@ucla.edu
  For Pittsburgh: ph_pitt023sms@ucla.edu
  For Memphis: ph_memphis023sms@ucla.edu

- **Password for all sites (case sensitive):** 023IDIConnect

2. Interviewer will indicate available hours in the shared Outlook calendar and site staff will be able to see conflicts in scheduling between each site.
3. Each site should add their appointment with their assigned colors as follows:
   - UAB: Green
   - Boston: Blue
   - Aurora: Orange
   - Bronx: Purple
   - Pittsburgh: Pink
   - Memphis: Red
4. Interviewer will confirm the appointment via email.
5. Notify interviewer of all changes or cancellations within 24 hours of the scheduled appointment, if possible.
6. If last minute changes do occur, please notify interviewer as soon as possible, by phone or text message.

Preparing for Interview

- Ensure the computer with a webcam is available in a private space, and has a headset with microphone plugged into the computer that is operational.
- Ensure the video system is ready and connected.
- Once participant is ready, notify interviewer by phone.

Initiating the Video Interview

- Interviewer will initiate a meeting by sending an email to the designated site staff.
- Click on the link in the email to join the meeting, log into the meeting using the study laptop, click join via computer, and turn on the video feed.
- Once the connection is established and the video feed is running, click to enlarge the video window.
- Help the participant get set up at the computer with the headset.
- Leave the room and close the door.

Ending the Video Interview

- Participant will notify you when the interview is done.
- Disconnect from the meeting

Section Appendix 14-2: SMS Messaging Guidelines

This section contains information on behavioral research procedures performed in MTN-023 around SMS message texting of participants to assess ring adherence and provide clinic visit reminders.

1. Overview

- These directions are intended to guide site staff on how to collect participant contact information in order for the participant to receive weekly SMS from BRWG staff.

Under the MTN-023 protocol, SMS will be sent to participants, weekly for the duration of the study. While date and timing will vary based on participant preference, messages will be programmed to send on the same day and at the same time every week.

Once participant cell phone numbers are collected, staff will test the participant's phone with the participants at enrollment.

2. Testing Participant Phone

Each participant who has consented to participate in the SMS notification option will have their cell phone capability tested at enrollment. While the participant is present, staff will complete the following steps to ensure the information provided is accurate and the SMS system will work properly with the participant's phone. Complete the following:

Site staff will send a text to the participant. The text should read "Test". Site staff will wait with participant to make sure she receives the text.

Once test text is received, participant will then be asked to respond to the text. Participant should respond with any number, for example, "1"or "2".

Site staff will wait to assess if participant is able to respond to texts.

3. Saving BRWG Contact in Participant Phone

BRWG staff will send each participant a weekly text. In order for participants to recognize who is sending the text, site staff will instruct participants to save the number from which BRWG will send text as a contact in their phone.

BRWG will send participant weekly texts using the phone number **(510) 619-1067.** This number was generated by the web-based text messaging software company Frontline. This is not the official contact for BRWG staff. This number will be used for the sole purpose of sending and receiving text for the study.

Study staff will inform participants that they can save the number in their contacts under a name they are most comfortable with, for example, "BRWG" or "Study".

4. Sending BRWG Participant Contact Information

Immediately following the enrollment visit of each new participant, study staff will provide BRWG with the participant's basic contact information (date or enrollment, PID and cell phone number).

BRWG will provide each site with a SMS contact tracking form. Site staff will fill this form out at the end of each new enrollment visit and will email the form to BRWG staff Janell Moore at jndmoore@ucla.edu

5. SMS Problem Troubleshooting

The study staff should contact Janell Moore via email at jndmoore@ucla.edu if they have any problems or questions about testing the participant's phone or filling out the contract tracking form. BRWG staff will contact the site staff if there are any problems with the contact information provided by the participants or any issues with sending/receiving texts